

REMARKS/ARGUMENTS

In the specification, the paragraphs at page 1, first paragraph, page 10, line 18 and page 11, line 4 have been replaced to correct typographical errors identified by the Examiner.

Claims 2-15 remain in this application. Claims 2 and 5 have been amended. The following issues are outstanding in the Office Action dated November 19, 2003:

1. Claims 3 and 4 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Claim 4 was necessarily rejected as being dependent upon claim 3;
2. Claims 1, 5 and 6 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/05873 ("Lina et al.");
3. Claims 2-4 and 7-9 were rejected as being unpatentable over Lina et al. in view of U.S. Patent Application Publication No. 2003/0077311 A1 ("Vyakarnam et al.") and U.S. Patent No. 5,621,035 ("Lyles et al.");
4. Claims 10-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al.; and
5. Claims 13-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of 4,614,794 ("Easton et al").

Each of these will be addressed in turn.

1. Rejection of Claims 3 and 4 Under 35 U.S.C. 112, First Paragraph

Applicants have described in the present written description how the foam is adhered to non-wound contacting surfaces. In particular, at least in the Abstract, the pad is described as having relatively few open cells in contact with the areas upon which cell growth is to be encouraged so as to avoid unwanted adhesions. In addition, such disclosures that are incorporated within the present application adequately enable one of skill in the art to make, use or sell the invention of claim 3 (and its dependent claims). *See, for example*, Figure 5 of commonly-owned U.S. Patent No. 5,636,643.

2. Rejection of Claims 1, 5 and 6 Under 35 U.S.C. 102(b)

Applicants have canceled claim 1, and amended claim 5 to depend on amended claim 2, which is allowable over the cited art as detailed below. Claim 6 likewise is indirectly dependent on amended claim 2. In view of such amendments, these claims are submitted to be allowable over Lina et al.

3. Rejection of Claims 2-4 and 7-9 Under 35 U.S.C. 103(a)

In this rejection, the Examiner stated that Vyakarnam et al. disclose that it is known to apply bioabsorbable polymer foams to various areas of the body in order to promote tissue regeneration. In addition, the Examiner stated Vyakarnam et al. disclose the use of a ceramic in combination with the foam in order to reinforce the foam such that the foam is strengthened so as to be structurally compatible with cancellous bone.

It is respectfully submitted that the purpose of Vyakarnam et al. is to provide a biocompatible *composite* made of a first fibrous layer attached to three-dimensional interconnected open cell porous foams that *have a gradient in composition and/or microstructure* through one or more directions. In fact, one of the objects of the application for invention of Vyakarnam et al. is to provide a biocompatible, bioabsorbable foam with *a continuous transitional gradient of morphological, structural and/or materials*. See, for example, page 1, paragraph [0007]; Abstract; all independent claims; paragraph [0034]; and many other places throughout Vyakarnam et al. The attachment of such a foam to another layer of material is further emphasized in Vyakarnam et al., which espouses the regeneration of tissue that mimics the mechanical and/or biological characteristics of blood vessels. See paragraph [0048].

Lyles et al. does not cure these deficiencies. Rather, Lyles et al. discloses novel and unique *filler compositions and enhanced dental materials* for use in dental applications—a nonanalogous art. Further, the preferred embodiment of the ceramic dental restorative material and filler composition (which does not define a continuous transitional gradient by any definition) is specifically stated in the Abstract as at least *four different materials* by weight. Lyles et al. further describes, generally, the process of manufacturing ultra low density fused-fibrous ceramic filler material. There is no suggestion, teaching, or motivation in Lyles et al. that would lead one of skill in the art to combine the process of Lyles et al. to create a gradient foam as taught in Vyakarnam et al., to then be substituted as the pad in Lina et al. (which teaches a porous pad), and thereby maintain the purpose of all three inventions.

Neither claim 2 nor claim 7 *combine* a ceramic with the pad, as urged by the application of Vyakarnam et al. with Lina et al. And using a ceramic or pad, alone, would destroy the

purpose of Vykarnam et al., which emphasizes a transitional gradient throughout the pad. The process of Lyles et al. offers no guidance to this emphasis. Likewise, if the foam of Vykarnam et al. were substituted into Lina et al., the gradient structure of the Vykarnam et al. foam would destroy the ability of Lina et al. to create sufficient negative pressure. Accordingly, because the gradient-forming purpose of Vykarnam et al. in combination with Lina et al. would inherently be destroyed—both because the substitution of the Vykarnam et al. foam alone fails to achieve the purpose, and the combination of Vykarnam et al. with Lina et al. likewise fails for the reasons set forth above, and because Lyles et al. offers no guidance as to maintaining the purpose of Vykarnam et al.—one of skill in the art would not be taught, motivated or otherwise discover the inventions of claim 2 and claim 7 to be obvious.

Claims 3 and 4, and claims 8 and 9, depending on claims 2 and 7, respectively, are submitted to be in condition for allowance for the same reason.

4. Rejection of Claims 10-12 Under 35 U.S.C. 103(a)

The Examiner cited Lina et al. as disclosing all the features of the claimed invention including the pad comprised of branched polymers, but excluding the pad comprised of bioabsorbable branched polymers. Vykarnam et al. was cited for its disclosure of bioabsorbably branched polymers because the polymers are particularly well-suited for tissue engineering.

But the problems with the combination of Vykarnam et al. (teaching a transitional gradient throughout the pad) with Lina et al. (teaching an open-pore pad) would still run counter to each other. That is, if you were to take the branched polymers in a transitional gradient of Vykarnam et al., and combine it with the open-pore pad of Lina et al. or substitute it therein, the

purpose of Vyakarnam et al. would be destroyed, as would the purpose of Lina et al. (sufficient negative pressure through the pad). Accordingly, neither of these references, alone or in combination, effectively teach, suggest, or motivate one of skill in the art to arrive at the inventions of claims 10-12, without destroying their intended purpose. As such, claims 10-12 are submitted to be nonobvious in view of the cited references.

5. Rejection of Claims 13-15 Under 35 U.S.C. 103(a)

Easton et al. was cited for its disclosure of a wound dressing (pad) comprising the biodegradable protein collagen, thereby teaching a cell-growth enhancing matrix for enhancing cellular growth. Claim 13 is directed to a biocompatible wound dressing comprising, inter alia, a pad comprised of a cell-growth enhancing matrix, an airtight seal removably adhered to said pad, and a negative pressure source in fluid communication with said pad.

The invention of Easton et al. is directed towards protein/polysaccharide *complexes*, and not to pure protein matrixes alone. Easton et al. teaches that the polysaccharides in the complex involve inflammatory reactions in the user of the complex. Col. 3, ll. 8-13. Combining the *complex* of Easton et al. with the pad of Lina et al. would result in potential inflammatory reactions, moreso than normal because Lina et al. teaches negative pressure *through* the pad/complex. Accordingly, one of skill in the art would necessarily avoid any matrix complex of protein/polysaccharide due to the negative therapeutical implications of such a combination. Each matrix complex would have to be meticulously manufactured to avoid any possibility of inflammatory reaction, which would be both costly and inefficient.

Because of these problems and costly, time-consuming additional efforts, one of skill in the art would actually avoid the combination of a protein/polysaccharide complex with the invention as disclosed in Linus et al. Accordingly, it is submitted that claim 13 is allowable in view of Lina et al. in view of Easton et al. For the same reasons, dependent claims 14-15 are submitted to be allowable.

Applicants submit further herewith an Information Disclosure Statement, and thank the Examiner for bringing the improper form of the listing of references in the specification to Applicants' attention.

Applicants have amended the specification, where indicated, to respond fully to the Office Action of November 19, 2003. No new matter has been added.

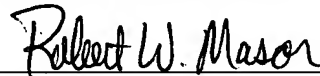
SUMMARY

Believing it has addressed all matters raised by the Examiner's November 19, 2003 Office Action, Applicants respectfully request timely action on the merits. No fees are believed to be required for the amendment. Nevertheless, the Commissioner is permitted to deduct or credit any fees that may be required from Kinetic Concept Inc. Deposit Account No. 500-326.

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

Applicants respectfully request favorable consideration.

Respectfully submitted,



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